OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
330 INDEPENDENCE AVENUE, SW G640
WASHINGTON, DC 20201

CONCERNING

Genentech Umbrella Agreement

Agreement No.: HHSO100201800036C
Total Amount of the Agreement: $357,249,006.00
Total Estimated Government Funding of the Agreement: (b)(4)
Total Estimated Recipient Funding of the Agreement: (b)(4)
Funds Obligated: (b)(4)
Effective Date: September 27, 2018
Period of Performance: September 27, 2018 thru September 26, 2023

Authority: 10 USC 2371 and Sections 319(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

Line of Accounting and Appropriation:

(b)(4)

This Agreement is entered into between the United States of America, hereinafter called the "Government", represented by the Department of Health and Human Services (HHS) and Genentech, Inc., hereinafter called "Recipient", pursuant to and under U.S. Federal law. Recipient and the Government are each referred to as a "Party" and collectively referred to as the "Parties".

FOR GENENTECH, INC.

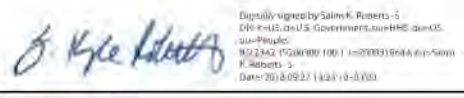
(b)(6)

(Signature)

(b)(6)

(Name, Title) (Date)

FOR THE UNITED STATES OF AMERICA
OFFICE OF ACQUISITION MANAGEMENT,
CONTRACTS & GRANTS SECRETARY
FOR PREPAREDNESS AND RESPONSE



(Signature)

S. Kyle Roberts, Other Transaction Agreement Officer, ASPR/BARDA September 27, 2018

(Name, Title) (Date)

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ARTICLES

ARTICLE I: SCOPE OF THE AGREEMENT

A. Introduction

- The objective of this Agreement, which is considered an Other Transaction Agreement (OTA), is to create a framework for collaboration between Recipient and the Biomedical Advanced Research and Development Authority (BARDA) to advance the development of (b)(4) (b)(4) To support this objective, Recipient will use commercially reasonable efforts to conduct studies to support regulatory approval of each selected product and device. (b)(4) (b)(4) (b)(4) This framework will provide the Parties with the flexibility to execute a portfolio approach to funding in the complex and uncertain environment of drug development.

- The initial work Under This Agreement will support regulatory approval of (b)(4) (b)(4)

- The Parties recognize that Recipient operates within a network of affiliated companies. However, before Recipient's rights and obligations Under This Agreement may be performed by or extended to such an Affiliate, such Affiliate must be listed in Attachment 3 of this Agreement and Recipient shall ensure that such Affiliate will comply with the terms and conditions of this Agreement. For clarity, an Affiliate will not be considered a Party to this Agreement by virtue of its participation.

- The Agreement may be modified by written mutual agreement of the Parties consistent with Article III.

- Building upon Recipient's current Medical Countermeasure and diagnostics R&D efforts, (b)(4) (b)(4) The Parties have developed detailed plans for advancement of these programs, with targeted outcomes over the Period of Performance, which may include the advancement of new compounds into clinical trials as well as clinical evaluation of a diagnostic platform. The current portfolio as well as ongoing assessment of external assets/technology provides for contingencies in the event of failures in development. Recipient has demonstrated expertise,

commitment, and resources to advance important therapies to combat existing and emerging biological and chemical threats.

- The Recipient's current portfolio aligns with both PHEMCE and BARDA's requirements. (b)(4) (b)(4) The Government recognizes that some drug candidates proposed for the portfolio are already in-licensed by Recipient and/or its Affiliates from third parties and subject to pre-existing third party agreements. Recipient recognizes that its drug candidates are not automatically approved for introduction into the portfolio and acceptance is subject to the Government's review and acceptance of the terms and conditions outlined in any applicable third party agreements. Consequently, Recipient will provide to the OTAO for the Government's review a copy of each third party agreement relevant to a proposed drug candidate prior to the introduction of such drug candidate into the portfolio. A public-private partnership between the Parties formed Under This Agreement will allow the technical and business risks of drug development to be mitigated and increase the probability of successful development and approval/licensure of novel Medical Countermeasures and diagnostics to address unmet medical needs.

B. Definitions

Affiliate: Is not a Sub-Recipient. Affiliates are only those entities identified in Attachment 3, all of which are a parent, subsidiary, or sister company of Recipient.

Agreement: The body of this Agreement and Attachments 1 – 3, which are expressly incorporated in and made a part of this Agreement.

(b)(4)

(b)(4)

Computer Software: Means

(1) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and
(2) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

Control: The term "Control" as used in this Agreement shall mean the ability of a Party to grant rights to Technology or supply materials to the other Party without violating the terms of any agreement that such Party might have with any other party.

Data: Recorded information within the Field, regardless of form or method of recording, which includes but is not limited to, technical data, Computer Software, and trade secrets, made in the performance of work Under This Agreement. However, the term does not include any financial, administrative, patient identification, cost, pricing or management information, even if made in the performance of work Under This Agreement.

Field: The development of assets to treat, diagnose, or prevent or provide countermeasures for biothreat infections, pandemic influenza, emerging infectious diseases, and chemical, biological, radiological or nuclear threats or exposures.

Financial Status Report: A report prepared by Recipient to address monthly costs.

Foreign Firm or Institution: A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government and firms, institutions or business organizations that are owned or substantially controlled by foreign governments, firms, institutions, or individuals. Specifically excluded from the definition of Foreign Firm or Institution are the entities listed on Attachment 3 along with their non-US affiliates.

Government: The United States of America, as represented by HHS.

Government Purpose Rights: The rights to use, duplicate, or disclose Data, in whole or in part and in any manner, for Government purposes only, and to have or permit others to do so for Government purposes only.

Invention: Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the United States Code.

Know-How: Information, practical knowledge, techniques, and skill development by Recipient in the performance of work Under This Agreement necessary for the Practical Application of a Subject Invention within the Field. Know-How does not include patents and patent applications.

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. HHS will ensure that any Data released or disclosed under Limited Rights is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose any Data that is subject to, or designated as falling within, Limited Rights outside the

Government, use such Data for competitive procurement or manufacture, release or disclose such Data for commercial purposes, or authorize such Data to be used by another party. The Parties shall maintain the confidentiality of all Data that is subject to, or designated as falling within, Limited Rights.

Limited Rights Data: Means

(1) Data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications; and/or

(2) Data in a notice reflecting a Subject Invention provided to the agency prior to the filing of a patent application (*See* Article X.B.(1).)

Made: The conception or first actual reduction to practice of the Invention.

Option: An option, entered into by mutual agreement of both Parties pursuant to a Statement of Work (SOW) and budget, by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the Agreement or may elect to extend the term of this Agreement.

Other Transaction for Advanced Research (OTAR): A legally binding, non-acquisition instrument (generally called an "agreement") used in instances where the principal purpose is the stimulation and/or support of advanced research and development, where a non-traditional Government awardee participates to significant extent in the work.

Other Transaction Agreement Officer (OTAO): Is the responsible Government official authorized to bind the Government by signing this Agreement and bilateral modifications.

Other Transaction Agreement Specialist (OTAS): Is a supporting official that executes agreement modifications on behalf of the OTAO.

Other Transaction Agreement Technical Representative (OTTR): Is the primary Government official for all technical matters on this Agreement.

Portfolio: The clinical candidates and diagnostic platform included Under This Agreement.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public for a regulatory approved product.

Program: Research and development being conducted by the Parties pursuant to this Agreement. Alternatively referred to as "Project."

Prohibited Sources: Restrictions administered by the Department of the Treasury on Acquisitions of Supplies and Services:

(a) Except as authorized by OFAC, agencies and their recipients and subrecipients must not acquire any supplies or services if any proclamation, Executive order, or statute administered by OFAC, or if OFAC's

implementing regulations at 31 CFR chapter V, would prohibit such a transaction by a person subject to the jurisdiction of the United States.

(b) Except as authorized by OFAC, most transactions involving Cuba, Iran, and Sudan are prohibited, as are most imports from Burma or North Korea into the United States or its outlying areas. In addition, lists of entities and individuals, subject to economic sanctions are included in OFAC's List of Specially Designated Nationals and Blocked Persons at http://www.treas.gov/offices/enforcement/ofac/sdn/. More information about these restrictions, as well as updates, is available in OFAC's regulations at 31 CFR Chapter V and/or on OFAC's Website at http://www.treas.gov/offices/enforcement/ofac.

Property: Any tangible personal property other than property actually consumed during the execution of work Under This Agreement.

Recipient: Genentech, Inc. (Genentech).

Subject Matter Expert (SME): Members of the BARDA technical team who provide technical insights into development activities being undertaken by the Recipient to satisfy the terms of this Agreement as set forth in the applicable SOW. BARDA generally enters into an agreement with an outside entity to gain the services of SMEs on a contractual basis. As non-Government employees, SMEs are subject to non-disclosure agreements as determined by each contract or agreement that they support.

Subject Invention: Any invention of the Recipient Made in the performance of work Under This Agreement.

Sub-Recipient: Any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Recipient or another Sub-Recipient for the performance of this Agreement.

Sub-Recipient Agreement: Any contract entered into by a Sub-Recipient to furnish supplies or services for the performance of this Agreement.

Technology: Discoveries, innovations, Know-How and Subject Inventions, whether patentable or not, conceived in the performance of work Under This Agreement and Controlled by Recipient, including Computer Software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, and copyrights developed Under This Agreement.

Under This Agreement: Means activities conducted pursuant to this Agreement that are Government funded or binding cost share by Recipient.

C. Scope

1. The Recipient shall perform an advanced research and development program (AR&D Program) in accordance with the SOW(s) incorporated in this Agreement as Attachment 1. The Recipient will submit or otherwise provide all documentation as required by Attachment 2, Reporting Requirements, unless mutually agreed otherwise by the Parties. The Parties acknowledge that the exercise of Options will be subject to the availability of funds. Before exercising an Option, the JOC will meet and the Parties will mutually agree on updates to the existing SOW, budget and cost share.

2. The Government will have involvement with the Recipient as set forth in the SOW. The Government will also obtain access to research results and certain rights in Data pursuant to Article IX and Attachment 2, Reporting Requirements. The Parties are bound to each other by a duty of good faith and commercially reasonable research effort in achieving the goals of the Program.

3. This Agreement is an "other transaction" pursuant to 42 U.S.C. §247d-7e (c)(4)(B)(iv). The Parties agree that the principal purpose of this Agreement is to support commercially reasonable efforts in advanced research in the development of Medical Countermeasure assets and not for the acquisition of Property or services for the direct benefit or use of the Government.

ARTICLE II: TERM

A. Term of this Agreement

This Agreement and the period of performance under it commences upon the date of the last signature and continues for a base period set forth in Attachment 1 ("Base Period") which may be extended by the Parties through exercise of up to 4 Options, for up to (b)(4) from the last signature date (the "Period of Performance," "POP" or "Term"). (b)(4) (b)(4) (b)(4) other Medical Countermeasure candidates within the Portfolio. The Government will give Recipient a preliminary written notice of its desire to exercise an Option at least ninety (90) days prior to the contemplated activation of a new Option. The Parties, through a JOC decision, may agree mutually to extend the Term and its Options beyond the (b)(4) maximum by written agreement on or before the expiration of the Term.

B. Termination Provisions

Either Party may terminate this Agreement for any reason or no reason by providing at least ninety (90) days prior written notice to the other Party, provided that such written notice is preceded by consultation between the Parties. In the event of a termination of the Agreement, it is agreed that disposition of Data shall be in accordance with the provisions set forth in Article IX, Data Rights. In the event of termination by either Party, the Recipient's and Government's termination costs shall be reimbursable pursuant to the terms of Article VI. Upon termination of this Agreement, the Government will also reimburse Recipient for its allowable costs and expenses, including, without limitation, non-cancellable allowable expenses and other costs and expenses incurred prior to or during the ninety (90) day notice period.

For purposes of this clause, termination costs shall be those costs identified in Federal Acquisition Regulation 31.205-42. The Government and the Recipient will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination, including disposition of animals acquired for research use. Failure of the Parties to agree to a reasonable adjustment will be resolved pursuant to Article VIII, Disputes. In the event of termination by the Government, all of the terms and conditions of this Agreement will expire and neither Party shall have any continuing obligations to perform Under This Agreement, except as provided in this Article with respect to the reimbursement of allowable and/or non-cancellable costs and expenses. In the event of termination by either Party all of the terms and conditions of this Agreement will expire, except for the

following provisions, which shall survive termination: Article IX, Sections A., B., D., and G. and Article X; and Article XI as specified in that Article.

C. Extending the Term

The Parties may extend by mutual written agreement the Term if funding is available and research opportunities, which are within scope, reasonably warrant. Any extension shall be formalized through modification of the Agreement by the OTAO and the Recipient. If the Recipient desires an extension to the Term, the Recipient shall submit a request in writing to the OTAO. Any request for an extension should include a revised milestone/project schedule (if applicable).

ARTICLE III: MODIFICATIONS

A. Recommendations for Modifications

As a result of quarterly meetings, annual reviews, or at any time during the Term, research progress or results may indicate that a change in the SOW would be beneficial to Program objectives. Any modification to the Agreement, excluding minor modifications discussed below, shall be by mutual written agreement of the Parties. Recommendations for modifications, including justifications to support any changes to the SOW, will be documented in a letter and submitted by the Recipient to the OTTR with a copy to the HHS OTAO and OTAS. This letter will detail the technical, chronological, and financial impact (if any) of the proposed modification to the Program.

B. Minor Modifications

For minor, non-material Agreement modifications without effect on any obligation of Recipient or the Government or the terms and conditions of this Agreement (e.g. changes in the paying office or appropriation data, etc.), the Government may make these types of changes unilaterally and no signature is required by the Recipient. The Parties agree that changes to key personnel identified in the Agreement shall be agreed upon by the JOC and OTAO and formalized by amendment if changes are under Article IV.

C. Amending the Agreement

The OTAO shall be responsible for agreeing to any modifications to this Agreement on behalf of the Government.

ARTICLE IV: MANAGEMENT OF THE PROGRAM

A. Recipient/Government Joint Oversight Committee

1. The Recipient/Government Joint Oversight Committee (JOC) is comprised of 2 senior level members from Recipient and 2 senior level Government participants. In addition, the OTAO, OTAS, and OTTR will attend as non-voting participants. The Parties may change the number of JOC participants upon mutual agreement provided that voting members remain equal between the Recipient and Government. Assuming no objection by the other Party, and upon advance written notice, additional representatives from either Party or external advisors may also be included in this body on an ad hoc

basis, as dictated by the circumstances. Either Party may substitute alternate senior level representatives, on either a temporary or an ongoing basis, by providing advance written notice.

JOC Members:

(b)(6)	
Christopher Houchens	Director (Acting) of CBRN Countermeasures
Ruben Donis	Deputy Director of IEIDD

Non-voting Attendees

Kyle Roberts	Other Transaction Agreement Officer
Karl Erlandson	Other Transaction Technical Representative

2. The responsibility of the JOC is to mutually interrogate risks, manage the progress of assets covered under the agreement, endorse potential new assets, and propose modifications to the allocation of funding across activities covered under the agreement.

3. The JOC will meet approximately every six (6) months or as necessary, by phone, video conference or in-person to review progress. The JOC will recommend the strategy to be covered under this Agreement during the subsequent funding period, as well as how Government and Recipient funding will be allocated across these activities. The recommendations would be submitted, as appropriate, to the relevant Recipient governance board(s) for endorsement and decision. If endorsed by the Recipient and by the Government, the recommendations will be incorporated into the SOW and this Agreement through modifications as described in Article III. In the event that a JOC decision cannot be reached, the matter will be escalated to one BARDA and one Recipient senior management member identified at the start of the Program in a good faith effort to achieve resolution. Final JOC decisions will be formalized in a memorandum and signed by both Parties.

B. Project Meetings

1. Project Teleconferences. A conference call between the OTTR and the Recipient's project leader shall occur bi-weekly, or as mutually agreed by the Parties. During this call, the project leader will discuss the activities undertaken during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The project leader may choose to include other key personnel on the conference call to give detailed updates on specific projects as may be requested by the OTTR. The OTTR or project leader may assign this responsibility to a delegate. The Recipient may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the OTTR.

2. Other Meetings. In addition to project teleconferences, Recipient and the Government shall participate in additional project meetings to coordinate the performance of the Agreement. These meetings may include face-to-face meetings with BARDA in Washington, D.C. and at work sites of the Recipient or any Sub-Recipients. Such meetings may include, but are not limited to, meetings of the Recipient (and Sub-Recipients invited by the Recipient) to discuss study designs, site visits to the Recipient's and Sub-Recipient's facilities, and meetings with the Recipient and HHS officials to discuss

the technical, financial, regulatory and ethical aspects of the Program. In order to facilitate review of Agreement activities, it is expected that the Recipient will provide data, reports, and presentations to Government personnel as reasonably requested by the OTTR. The Recipient shall provide itinerary/agenda at least five (5) business days in advance of any face to face meeting. The Recipient shall notify the OTTR of formal and informal correspondence with the Food and Drug Administration (FDA) or other regulatory agencies directly related to the Portfolio assets as specified in Attachment 2. For avoidance of doubt, Recipient shall not be required to notify OTTR of any correspondence that does not materially impact a Program or that contains materials unrelated to the performance of this OTA. Recipient shall provide OTTR with un-redacted correspondences that materially impact a Program. To the extent that a relevant correspondence also contains information unrelated to the performance of this OTA, Recipient shall redact only those portions of the correspondence that are not relevant.

3. In Process Review Meeting (IPR). On an annual or event driven basis, or prior to the exercise of Options, the Government may invite the Recipient to give a presentation at an IPR attended by BARDA, and select, invited interagency representatives and other interested Government parties, as needed. The Recipient will present Data. Successes and challenges of the Program will be discussed, and plans for the future will be presented.

4. The Parties understand that SMEs may be present at Government meetings as it relates to this Agreement. The SMEs are subject to nondisclosure agreements and will comply with the terms and conditions of this Agreement.

C. Document Review

The Recipient shall provide the Government sufficient opportunity to review study protocols, reports, regulatory and draft correspondence as set forth in Attachment 2. The Government's review and comments on these documents are non-binding and advisory in nature. Specific timelines for document review and responses are outline in Attachment 2, Reporting Requirements.

ARTICLE V: AGREEMENT ADMINISTRATION

A. Administrative and contractual matters under this Agreement will be referred to the following representatives of the Parties:

Government Points of Contact

(b)(0)

Recipient Points of Contact

(b)(0)

B. Technical matters Under This Agreement will be referred to the following representatives:

Government Points of Contact

Karl Erlandson, OTTR
Project Office, Therapeutics branch, Influenza and Emerging Infectious Diseases Division
202-692-4676
Karl.Erlandson@hhs.gov

Alternate OTTR:
Kim Armstrong
Branch Chief (Acting), Influenza and Emerging Infectious Diseases Division
202-260-0130
Kimberly.Armstrong@hhs.gov

Recipient Points of Contact

(b)(6)

Genentech, Inc.
1 DNA Way, South San Francisco, CA 94080

(b)(6)

ARTICLE VI: COST SHARING

A. The terms of this Article VI apply to the cost sharing for the Base Period (CLIN 0001, 0003) for the Program. This framework may be applied by mutual agreement to any of the Options or to any modifications to the effort required under the Base Periods. The Parties acknowledge that the exercise of Options will be subject to the availability of funding.

B. Recipient estimates that the cost of completing the Base Period is (b)(4) This amount reflects Recipient's estimate and may overstate or understate the actual cost of completing Base Period (b)(4) The Recipient agrees to fund approximately (b)(4)

(b)(4)

C. The total project cost of completing the activities during the Base Period (b)(4) shall include all costs incurred by the Recipient in connection with the work performed during Base Period (b)(4) Such costs shall be reflected in Recipient's Financial Status Report. The Government's projected obligation for Base Period (b)(4)

TOTAL PROJECT COST SUMMARY FOR BASE PERIOD

	(b)(4)
DIRECT LABOR	
FRINGE BENEFITS	
OVERHEAD	
SUBCONTRACTS	
MATERIALS	
DIRECT TRAVEL	
OTHER DIRECT COSTS	
G&A	
TOTAL COSTS	

COST SHARE FOR BASE P
RECIPIENT

DIRECT LABOR	
FRINGE BENEFITS	
OVERHEAD	
SUBCONTRACTS	
MATERIALS	
DIRECT TRAVEL	
OTHER DIRECT COSTS	
G&A	
TOTAL COSTS	

US GOVERNMENT

DIRECT LABOR	
FRINGE BENEFITS	
OVERHEAD	
SUBCONTRACTS	
MATERIALS	
DIRECT TRAVEL	
OTHER DIRECT COSTS	
G&A	
TOTAL COSTS	

PROJECTED FUNDING PROFILE

CLIN	Type	Segment	Area	Total Program	Government Share
(b)(4)					

D. BARDA will reimburse Recipient for approved costs Under This Agreement during the Base Period(s) (and subsequent Option periods, if exercised) up to the applicable "Government Share" amount set forth in Paragraph C of this Article.

E. Recipient will provide a Financial Status Report to the Government, which will, among other things, identify the total actual costs of performing this Agreement. This report is for informational purposes only. Recipient's accounting for government-reimbursed and Recipient costs shall be in accordance with Recipient's accounting practices but must comply with International Financial Reporting Standards (IFRS). Recipient's accounting methods to determine total actual costs are not required to comply with the Cost Accounting Standards or the cost principles at Federal Acquisition Regulation Subpart 31.2; however, Recipient must comply with the cost principles set forth in Article VII for Government reimbursed costs.

F. For purposes of the Financial Status Report, Recipient shall report Recipient's costs of performing this Agreement using the indirect rates identified in its April 17 2018 Cost Proposal to determine its actual costs for the duration of the Base Period.

G. Recipient's entitlement to reimbursement for approved costs Under This Agreement is not contingent upon Recipient's cost share equaling any specific ratio or percentage of total costs. The Parties' remedy to address the total cost exceeding or falling below the estimated total cost to perform the SOW is to agree to a mutual modification of the Agreement or termination of the Agreement.

ARTICLE VII: OBLIGATION AND PAYMENT

A. Obligation

The Government's liability to make payments to the Recipient is limited to only those funds obligated under Paragraph C of Article VI of this Agreement during performance of the contract, by modification to this Agreement, or as otherwise expressly stated in this Agreement. As of the commencement of this Agreement, the Government's obligated funds are for the Base Periods only. Each of the (b)(4) periods set forth in Article VI is subject to the availability of funds and written agreement of the Parties. The Parties agree that the Options do not represent an obligation by the Government or Recipient until exercised, following a negotiation on scope and cost.

B. Payments

The Recipient has and agrees to maintain an established accounting system that complies with International Finance Reporting Standards ("IFRS") and the requirements of this Agreement, and shall ensure that appropriate arrangements have been made for receiving, distributing and accounting for Federal funds received hereunder. An acceptable accounting system is one in which all costs, cash receipts and disbursements for which the Recipient is entitled to reimbursement under Article VI are controlled and documented properly. The Recipient will invoice the Government on a monthly basis in accordance with this Article VII. The Recipient's shared costs incurred during the reporting period shall be reported in the Financial Status Report and on monthly invoices. The Recipient's properly prepared invoice(s) will be submitted for payment not more than once per month in Adobe Acrobat (.pdf) format. The invoice shall be uploaded to a shared electronic file server (i.e., e-room), with an email copy to the OTAO, OTAS, OTTR, and PSC (Program Support Center) as cited below. If directed by the OTAO, the invoice shall be accompanied by appropriate documentation to support the payment request; however, Recipient will be required to prepare and maintain records, with supporting documentation that is consistent with commercial practices. Each invoice must contain the following information in order to be deemed properly prepared:

1. Name and address of Recipient
2. Invoice date and invoice number
3. Agreement number
4. Description, quantity, unit of measure, unit price, and extended price (if applicable)
5. Recipient cost share
6. Name and address of OTAR official to whom voucher is to be sent
7. Name, title, phone number, and mailing address of person to notify in the event of a defective invoice
8. Taxpayer Identification Number (TIN)
9. Electronic funds transfer (EFT) banking information
10. Conversion of foreign currency using Recipient's current internal foreign currency translation method actually used on a consistent basis in preparing its audited financial statements. The Recipient will convert foreign currency costs to US dollars each month using the closing spot exchange rate published by Reuters on the last working day of each month
11. Monthly invoices must include cumulative total costs submitted for reimbursement to date, adjusted (as applicable) to show any amounts suspended by the Government

Documents should be delivered to the OTAO, OTAS, OTTR, PSC, and e-room electronically. Unless otherwise specified by the OTAO, all deliverables and reports furnished to the Government Under This Agreement (including invoices) shall be addressed as follows:

NAME	E-mail invoices to:	Address
(b)(6) (OTAO)		ASPR – AMCG (b)(6) O'Neil House Office Bldg. 200 C Street, SW Washington, D.C. 20515

(b)(6)		ASPR – BARDA
(OTTR)		O'Neil House Office Bldg. Washington, D.C. 20515
PSC	PSC_Invoices@psc.hhs.gov	
E-Room:	TBD	

The Recipient agrees to promptly notify the OTAO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the Base Periods or any Option and the reasons for the variance.

The Government will pay in US dollars all proper invoices within 30 days of receipt or pay interest on any amounts due in accordance with the Prompt Payment Act.

C. Limitation of Payments

It is herein understood and agreed that Government funds are to be used solely for this Agreement and must be reasonable in nature and amount. The following cost principles shall be used for determining the allowability of costs for which reimbursement is sought by Recipient. These cost principles are not applicable to Recipient's contribution and the Financial Status Report.

1. Allocability shall be determined in accordance with the standards set forth in FAR 31.201-4. The Cost Accounting Standards do not apply to the Recipient or any Sub-Recipient. Costs shall be accounted for in accordance with the Recipient's or Sub-Recipient's commercial accounting practices.

2. To be reasonable, a cost must: be generally recognized as an ordinary or necessary part of the business; follow sound business practices; follow what a prudent business person would accept; comply with federal, state, and local laws; and be consistent with the Recipient's or the Sub-Recipient's established practices.

3. In addition, Recipient's costs that are passed onto the Government for reimbursement shall comply with the procedures and cost principles set forth in this paragraph:

Reimbursement is subject to restrictions on allowable costs described in FAR 31.2 unless otherwise stated here:

i. The cost principles set forth in FAR 31.2 shall only apply to the reimbursement of direct costs under cost-type Sub-Recipient Agreements. These cost principles will be applicable to the pricing of fixed priced Sub-Recipient Agreements only to the extent required by FAR 31.102.

ii. A cost-type Sub-Recipient may propose indirect rates as a component of its proposal to Recipient. The Government will review these indirect rates as part of the Sub-Recipient approval process set forth in Article XIII. The Government's approval to issue the Sub-Agreement constitutes the Government's agreement that the proposed

indirect rate(s) may be used during the performance of the Sub-Agreement to determine the Sub-Recipient's reimbursable indirect costs. The approved indirect rate(s) will not be subject to audit or adjustment based upon the Sub-Recipient's actual cost experience during the performance of the Sub-Agreement.

iii. Invoicing and reimbursement for employees of Recipient that perform work under this Agreement will be based on current accounting practices at Recipient. Specifically, reported and reimbursed expenses will include: a) aggregate reported time of individuals working under this Agreement in a specified functional group and at a specified level of compensation during the reporting period; and b) the aggregate average salary of individuals working within the specified functional group at the specified level of compensation.

D. Financial Records and Reports

As directed by the OTAO, the Recipient shall maintain records in accordance with commercially acceptable business practices to account for all funding Under This Agreement and shall maintain records in accordance with commercially acceptable business practices to account for Recipient funding provided Under This Agreement in support of the Financial Status Report required under Article VI. Upon completion or termination of this Agreement, whichever occurs earlier, the Recipient shall furnish to the OTAO a copy of the Final Technical Report required by Attachment 2, Section D: Deliverables. The Recipient's relevant financial records are subject to examination or audit on behalf of HHS by the Government for a period not to exceed four (4) years after expiration or earlier termination of the Term. The OTAO or designee shall have direct access to complete records and information of the Recipient, to the extent necessary to audit to ensure full accountability for all amounts reimbursed by the Government Under This Agreement. Such audit, examination, or access shall be performed during business hours on business days upon at least six weeks prior written notice and shall be subject to the security requirements of the audited party.

E. Comptroller General Access to Records

To the extent that the total Government payment Under This Agreement exceeds $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine Recipient records relating to performance Under This Agreement and of any entity that participates in the performance of this Agreement for a period of four (4) years after final payment was made. This requirement shall not apply with respect to any entity that participates in the performance of the Agreement that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a Government entity in the year prior to the date of this Agreement. This Paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. Recipient shall ensure that its Sub-Recipient agreements are consistent with this Article.

ARTICLE VIII: DISPUTES

A. General

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

B. Dispute Resolution Procedures

1. For any disagreement, claim or dispute between the Parties concerning questions of fact or law arising from or in connection with this Agreement, whether or not involving an alleged breach of this Agreement, the Parties agree to make a good faith effort to utilize the procedures described in Subparagraphs 2, 3 and 4 of this Paragraph B.

2. Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding, which was known, or should have been known, more than six (6) months prior to the notification made under Subparagraph B.3 of this Article constitute the basis for relief under Subparagraph B.3 of this Article. Either Party may waive this requirement in writing. Any waiver on behalf of the Government shall be made by the Head of Contracting Activity for ASPR.

3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the OTAO or the Recipient, as the case may be) in writing of the relevant facts, identify unresolved issues, and specify the clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the Assistant Secretary for Preparedness and Response (ASPR) Head of Contracting Activity (HCA) and a Recipient senior executive appointed by the Recipient. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The ASPR HCA and the Recipient senior executive shall conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such written position.

4. In the absence of a joint decision, upon written request to the HHS Senior Procurement Executive (SPE), made within thirty (30) calendar days of the expiration of the time for a decision under Subparagraph B.3 above, the dispute shall be further reviewed. The SPE may elect to conduct this review personally or through a designee or jointly with a senior executive appointed by the Recipient. Following the review, the Chief Acquisition Officer or designee will resolve the issue(s) and notify the Parties in writing. If a decision has not been made within 120 days, the request may be deemed denied.

5. The Parties stipulate that any decision reached under Subparagraph B.4 of this Article, including a deemed denial, may be submitted to the Court of Federal Claims to the extent permitted by law.

6. The pendency of a dispute shall not interfere with each Party's right to terminate the Agreement pursuant to Article II.B and recover any resulting terminations costs.

C. Limitation of Damages

Except for claims of non-payment of amounts due under Article VI, any claims for damages of any nature whatsoever pursued Under This Agreement shall be limited to direct damages only up to the aggregate amount of Government funding disbursed as of the time the dispute arises. In no event shall the Parties be liable for claims for consequential, punitive, special and incidental damages, claims for lost profits, re-procurement costs, or other indirect damages. Either Party may recover interest on any amounts submitted for payment and denied during the disputes process. Interest on an amount found due on a disagreement, claim or dispute shall be paid for the period beginning with the date the HHS Senior Procurement Executive receives a request for a joint decision made pursuant to Subparagraph B.3 of this Article until the date of payment of the claim. Simple interest shall accrue and be paid at the same rate as that which the Secretary of the Treasury shall specify as applicable for each successive 6-month period under the Prompt Payment Act.

ARTICLE IX: DATA RIGHTS

A. Allocation of Principal Rights

1. The Government shall have unlimited rights for use in the Field in—
   (i). Preexisting data funded by the Government. For clarity, Government rights in any preexisting data produced by Recipient and funded by the Government under a separate agreement shall be governed by such separate agreement, and this Agreement shall not alter any Government rights in such data produced outside of this Agreement.
   (ii). Data first produced in the performance of this Agreement exclusively with Government funds
   (iii). Form, fit, and function data delivered under this Agreement;
   (iv). Data delivered under this Agreement (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this Agreement; and

2. The Government shall have Government Purpose Rights to all data produced in performance of this contract that was funded jointly by both parties under the cost sharing arrangement contained in this Agreement
3. The Government shall have Limited Rights to (a) all data, other than restricted computer software, that embody trade secrets or are commercial or financial and confidential or privileged, that pertains to items, components, or processes developed at private expense in the performance of this Agreement, and (b) data contained in a disclosure of a Subject Invention provided to the agency prior to the filing of a patent application. (See Article X.C. (1).)

B. Parties' Obligations

1. Recipient agrees to retain and maintain in good condition all Data necessary to achieve Practical Application of any Subject Invention in accordance with the Recipient's established record retention practices. In the event of exercise of the Government's March-in Rights as set forth under Article X, Paragraph H, Recipient agrees, upon written request from the Government, to deliver at no

additional cost to the Government, all existing Data necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request. The Government shall obtain Government Purpose Rights to this delivered Data, except for Data subject to Limited Rights as identified herein.

2. Recipient's right to use Data includes the right under Recipient's established business policies to make public research data (especially human research data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis. Recipient's publication of Data disclosing any Subject Invention shall trigger Recipient's obligation to file an application for a patent to such Subject Invention per Article X.B.3.

C. Marking of Data

1. Recipient will mark any Data delivered under this Agreement with Limited Rights with the following legend. (See Article IX.A.(3) above.):

"LIMITED RIGHTS" The Government's right to use, modify, reproduce, perform, display, or disclose this Data is limited to the reproduction, preparation of derivative works, including derivative works necessary to manufacture selected medical countermeasure candidates in the Portfolio for use by the Government in the Strategic National Stockpile, distribution of copies to the public, and performing publicly and displaying publicly by or on behalf of the Government.

2. **Lower Tier Agreements**

The Recipient shall ensure that any agreement entered into after the execution of this Agreement with an Affiliate or Sub-Recipient (regardless of tier) for any experimental, developmental, or research work that will be submitted for reimbursement Under This Agreement is consistent with this Article.

The Recipient shall execute modifications to its existing third party agreements under which a Sub-Recipient will perform any experimental, developmental, or research work that will be submitted for reimbursement Under This Agreement to ensure compliance with the terms and conditions outlined herein within 90 days of the execution of this Agreement.

3. **Identification and Disposition of Data**

The Recipient shall keep copies of all Data required by the FDA relevant to this Agreement for the time specified by the FDA. In addition, the Recipient shall provide regulatory data to the OTTR and OTAS in accordance with Attachment 2, Reporting Requirements. The Government reserves the right to review any other data determined by the Government to be relevant to this Agreement. The Government further acknowledges that Recipient holds the commercialization rights for all products developed Under This Agreement and will be responsible for their registration with the FDA.

4. **Publication and Publicity**

No Data shall be released or publicized without concurrence from the Recipient. For purposes of this Agreement, the term "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing Data must be submitted to the Recipient and the OTTR for review

and comment no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. The Government's support shall be acknowledged in all such publications substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under OT number: HHSO100201800036C."

5. **Review of Press Releases**

All Parties agree to accurately and factually represent the work conducted Under This Agreement in all press releases. Misrepresenting results or releasing information that is injurious to the integrity of a Party may be construed as improper conduct. The term "Press releases" shall be defined as the public release of information via any medium, excluding peer-reviewed scientific publications. Each Party agrees to provide the other Party with an advance copy of any press release related to this Agreement not less than ten (10) business days prior to the issuance of the press release. BARDA support shall be acknowledged in all such press releases substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under OT number: HHSO100201800036C."

6. **Confidential Information**

Unless other terms and conditions outlined within this Agreement apply, each Party may receive Information from the other Party during the Term of this Agreement. The term "Information" shall mean any and all information, Data or Know-How, whether technical or non-technical, oral or written, that is disclosed by one party ("Disclosing Party") to the other party ("Receiving Party"). For a period of ten (10) years from the date of disclosure of a given item of Information, the Receiving Party agrees:

1. To use the Information only in connection with its performance of this Agreement;

2. To treat the Information as it would its own proprietary and confidential information;

3. To disclose the Information only to employees or agents of Receiving Party who are providing services hereunder and who agree to be bound by these confidentiality obligations; and

4. To take all reasonable precautions to prevent the disclosure of Information to any third-party other than an Affiliate or Sub-Recipient without the prior written consent of the Disclosing Party.

Each Party shall be relieved of its obligations under this Paragraph if the Information:

1. Was known to the Receiving Party or its Affiliate or Sub-Recipient prior to receipt hereunder and without a duty of confidentiality as set forth in written records; or

2. Is generated by the Receiving Party or its Affiliate or Sub-Recipient by persons who have not had access to or knowledge of the Information disclosed hereunder; or

3. At the time of disclosure by the Disclosing Party to the Receiving Party, was generally available to the public, or which after disclosure hereunder becomes generally available to the public through no fault attributable to the Receiving Party; or

4. Is hereafter made available to the Receiving Party or its Affiliate or Sub-Recipient for use or disclosure by the Receiving Party from a third party having a right to do so; or

5. Is required by law, regulation, subpoena, or judicial or governmental order to be disclosed, provided that the Receiving Party gives the Disclosing Party sufficient notice to permit Disclosing Party to seek a protective order or other similar order with respect to such Information.

ARTICLE X: PATENT RIGHTS.

A. Allocation of Principal Rights and Obligations

1. *Ownership*. Recipient shall retain ownership of each Subject Invention throughout the world, unless (i) Recipient shall have notified the OTAO that Recipient does not intend to retain ownership of such Subject Invention in accordance with paragraph B(2) of this Article, (ii) Recipient fails to disclose such Subject Invention to the OTAO in accordance with paragraph B(1) of this Article, or (iii) Recipient fails to file a patent application for such Subject Invention in accordance with paragraph B(3) of this Article, in which case ownership shall vest with the Government.

2. *License to Government For Subject Inventions To Which Recipient Retains Ownership*. With respect to any Subject Invention Made Under This Agreement in which Recipient retains title, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. For clarity, this license does not include the right to use or allow others to use the Subject Invention for commercial purposes.

3. *License to Recipient for Subject Inventions to which Recipient Does Not Elect to Retain Ownership*.

i. In the event that Recipient does not elect to retain ownership in a Subject Invention pursuant to paragraph B(2) of this Article, Recipient shall retain a nonexclusive royalty-free license throughout the world in such Subject Invention to which the Government obtains title pursuant to section C of this Article, unless Recipient fails to disclose the invention within the times specified in paragraph B(1) of this Article. Recipient's license extends to any domestic subsidiaries and affiliates within the corporate structure of which Recipient is a part, and includes the right to grant sublicenses to the extent Recipient was legally obligated to do so at award of this OTA. The license is transferable only with the written approval of the Government, except

when transferred to the successor of that part of the Recipient's business to which the invention pertains.

ii. Recipient's license may be revoked or modified by the Government to the extent necessary to achieve expeditious practical application of the Subject Invention in a particular country in accordance with the procedures outlined under Article X A. (2)(iii).

iii. Third Party Application

a. In response to a third party's proper application for an exclusive license, Recipient's domestic license may be revoked or modified to the extent necessary to achieve expeditious practical application of the Subject Invention. The application shall be submitted in accordance with the applicable provisions in 37 CFR part 404 and agency licensing regulations. Recipient's license will not be revoked in that field of use or the geographical areas in which the Recipient has achieved practical application and continues to make the benefits of the Subject Invention reasonably accessible to the public. The license in any foreign country may be revoked or modified to the extent the Recipient, its licensees, or its domestic subsidiaries or affiliates have failed to achieve practical application in that country.

b. Revocation or modification of Recipient's minimum rights. Before revoking or modifying Recipient's license in accordance this Article, the OTAO shall furnish the Recipient a written notice of intention to revoke or modify the license. The Government shall allow Recipient at least 30 days (or another time as may be authorized for good cause by the OTAO) after the notice to show cause why the license should not be revoked or modified. Recipient has the right to appeal, in accordance with applicable regulations in 37 CFR part 404 and agency licensing regulations, any decisions concerning the revocation or modification

4. *License To Recipient For Subject Inventions To Which Recipient Has Elected To Retain Ownership But Does Not File a Patent Application or does Not Prosecute a Patent Application*.

i. In the event that Recipient has elected to retain ownership of a Subject Invention but subsequently elects not to file a patent application for the Subject Invention or elects not to prosecute a patent application for the Subject Invention, Recipient shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title, except if Recipient fails to disclose the Subject Invention within the times specified in Paragraph B of this Article. The Recipient's license extends to the Recipient's subsidiaries and Affiliates, if any, within the corporate structure of which Recipient is a party and includes the right to grant licenses of the same scope to the extent that Recipient was legally obligated or permitted to do so at the time the Agreement was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of Recipient's business to which the Subject Invention pertains. The Government approval for license transfer shall not be unreasonably withheld. For the purposes of this Paragraph, references to Recipient's subsidiaries and Affiliates shall not be limited to the entities identified in Attachment 3.

ii. The Recipient's license under this Paragraph may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted

consistent with appropriate provisions at 37 CFR Part 404. Recipient's license shall not be revoked in that field of use or the geographical areas in which Recipient has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

iii. Before revocation or modification of Recipient's license under this Paragraph, the Government shall furnish Recipient with a written notice of its intention to revoke or modify the license, and Recipient shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

B. Recipient's Obligations

1. Recipient shall disclose in writing each Subject Invention to the OTAO within one (1) year after the inventor discloses it in writing to Recipient personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this Agreement under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The parties agree that the information contained in the disclosure shall qualify as limited rights data as defined under Article I B of this Agreement, and is not subject to further disclosure without mutual agreement by both parties. Both parties agree that such disclosure remains confidential pending filing of a patent application per Article X(B)(3) below.

2. The Recipient shall elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTAO within two (2) years of disclosure to the agency under Article X.B.(1) above. However, in the event that Recipient's publication or use of the data as provided under Article IX.B. has initiated the 1 year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 calendar days prior to the end of the statutory period.

3. The Recipient shall file either a provisional or a non-provisional patent application on an elected Subject Invention within 1 year after election. If the Recipient files a provisional application, it shall file a non-provisional application within 12 months of the filing of the provisional application. The Recipient shall file patent applications in additional countries (or international patent offices within either 12 months of the first filed patent application or 6 months from the date permission is granted by the Commissioner of Patents to file foreign patent applications, where such filing has been prohibited by a Secrecy Order.

4. The Recipient may request extensions of time for disclosure, election, or filing under paragraphs (B).(1), (B).(2), and (B).(3) of this clause.

C. Conditions When the Government May Obtain Title

Upon the Government's written request, Recipient shall convey title to any Subject Invention to the Government under any of the following conditions:

1. If Recipient fails to disclose or elects not to retain title to the Subject Invention within the times specified in Paragraph B of this Article; provided, that the Government may only request title

within sixty (60) calendar days after learning of the failure of Recipient to disclose or elect within the specified times.

2. In those countries in which Recipient fails to file patent applications within the times specified in Paragraph B of this Article; provided, that if Recipient has filed a patent application in a country after the times specified in Paragraph B of this Article, but prior to its receipt of the written request by the Government, Recipient shall continue to retain title in that country; or

3. In any country in which Recipient decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceedings on, a patent on a Subject Invention.

D. Action to Protect the Government's Interest

Recipient agrees to execute or to have executed and promptly deliver to the Government all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which Recipient elects to retain title and (ii) convey title to the Government when requested under Paragraph D of this Article and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

1. Recipient agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by Recipient, each Subject Invention made Under This Agreement so Recipient can comply with the disclosure provisions of Paragraph C of this Article. Recipient shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars. Recipient also agrees to instruct all employees, in accordance with its regular business practices, on the need to maintain confidentiality of any information covered by the disclosure under Paragraph (B)(1) of this Article.

2. Recipient shall notify the Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

Recipient shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement HHSO100201800036C, awarded by HHS. The Government has certain rights in the invention."

E. Lower Tier Agreements

The Recipient shall ensure that any agreements entered into after the execution of this Agreement with an Affiliate or Sub-Recipient (regardless of tier) for any experimental, developmental, or research work that will be submitted for reimbursement Under This Agreement are consistent with this Article.

The Recipient shall execute modifications to its existing third party agreements under which a Sub-Recipient will perform any experimental, developmental, or research work that will be submitted for

reimbursement Under This Agreement to ensure compliance with the terms and conditions outlined herein within 90 days of the execution of this Agreement.

F. Reporting on Utilization of Subject Inventions

1. Recipient agrees to submit, during the Term, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Recipient or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Recipient also agrees to provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with Paragraph H of this Article. Consistent with 35 U.S.C. § 202(c)(5), the Government agrees it shall not disclose such information to persons outside the Government without permission of Recipient.

2. All required reports shall be submitted to the e-room, OTAS, OTAO, and OTTR.

G. March-in Rights

The Recipient agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require Recipient, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license within the Field to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Recipient, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license within the Field itself if the Government determines that:

1. Such action is necessary because Recipient or assignee has not taken effective steps, consistent with the intent of this Agreement, to achieve Practical Application of the Subject Invention; or

2. Such action is necessary to alleviate health or safety needs, which are not reasonably satisfied by Recipient, assignee, or their licensees.

ARTICLE XI: FOREIGN ACCESS TO TECHNOLOGY

This Article shall remain in effect during the Term and for five (5) years thereafter.

A. General

The Parties agree that research findings and technology developments arising Under This Agreement may constitute a significant enhancement to the national security and to the economic vitality of the United States. Accordingly, access to important technology developments Under This Agreement by Foreign Firms or Institutions must be carefully controlled. The Recipient agrees to comply with all applicable laws regarding export controls and not to export any Technology to any US embargoed countries.

The Recipient shall provide timely notice to the Government of any proposed transfers from the Recipient of Technology developed Under This Agreement to Foreign Firms or Institutions; provided that, this Article shall not apply to transfers by Recipient of Technology to Affiliates or as part of the sale, merger, or acquisition of Recipient, or as part of the sale or transfer of that part of Recipient's business to which the Technology developed Under This Agreement pertains. If the Government determines that

a transfer may have adverse consequences to the national security interests of the United States, the Recipient, its vendors, and the Government shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which provide substantially equivalent benefits to the Recipient.

In any event, the Recipient shall provide written notice to the OTTR and OTAO of any proposed transfer to a Foreign Firm or Institution at least thirty (30) calendar days prior to the proposed date of transfer. Such notice shall cite this Article and shall state specifically what is to be transferred and the general terms of the transfer. Within fifteen (15) calendar days of receipt of the Recipient's written notification, the OTAO shall advise the Recipient whether it consents to the proposed transfer. In cases where the OTAO does not consent to the proposed transfer or the OTAO provides no decision within the fifteen (15) calendar days after receipt of Recipient's notice, the Recipient may utilize the procedures under Article VI, Disputes. However, no transfer shall take place until a decision is rendered.

In the event of a transfer of Technology by Recipient to a Foreign Firm or Institution which is identified as a Prohibited Source pursuant to Federal Acquisition Regulation Subpart 25.7: (a) the Government may terminate this Agreement for cause and (b) the Government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Technology throughout the world for Government and any and all other purposes, particularly to effectuate the intent of this Agreement. Upon request of the Government, the Recipient shall provide written confirmation of such licenses.

B. Lower Tier Agreements

The Recipient shall ensure that any agreements entered into after the execution of this Agreement with an Affiliate or Sub-Recipient (regardless of tier) for any experimental, developmental, or research work that will be submitted for reimbursement Under This Agreement are consistent with this Article.

The Recipient shall execute modifications to its existing third party agreements under which a Sub-Recipient will perform any experimental, developmental, or research work that will be submitted for reimbursement Under This Agreement to ensure compliance with the terms and conditions outlined herein within 90 days of the execution of this Agreement.

ARTICLE XII: TITLE TO AND DISPOSITION OF PROPERTY

The Government is reimbursing the Recipient for the approved costs up to the limits set forth in Article VI, and Government funding may be used to acquire Property as described in this Agreement and Attachment 1.

ARTICLE XIII: SUB-RECIPIENTS

For any firm-fixed price, time and materials, or labor hour Sub-Recipient agreement with a value in excess of $500,000, the Recipient will provide the OTAO the opportunity to review all Sub-Recipient agreements and related justification for cost or price reasonableness ten (10) calendar days before execution. This shall include the nature of the work that the Sub-Recipient is going to perform, an estimated duration of the work, and the proposed costs for the work. The OTAO will submit a written response within ten (10) calendar days stating approval or disapproval of the Sub-Recipient agreement. In the event that the OTAO disapproves of the Sub-Recipient agreement, the OTAO must provide

written justification to support his/her decision. If a written response is not provided by the OTAO within ten (10) calendar days, the Recipient will elevate concerns to the AR&D Section Chief to immediately address the outstanding request. Recipient will provide the OTAO with an electronic copy of the final Sub-Recipient agreement.

ARTICLE XIV: CIVIL RIGHTS ACT

Performance of this Agreement in the U.S. is subject to the compliance requirements of Title VI of the Civil Rights Act of 1964 as amended (42 U.S.C. 2000-d) relating to nondiscrimination in Federally assisted programs. The Recipient has signed an Assurance of Compliance with the nondiscriminatory provisions of the Act.

ARTICLE XV: EXECUTION

This Agreement may be revised only by written consent of the Recipient and the HHS OTAO. This Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

ARTICLE XVI: SPECIAL CLAUSES

Unless otherwise noted, performance of this Agreement in the U.S. is subject to the following Special Clauses:

A. Protection of Human Subjects

1. The Recipient agrees that the rights and welfare of human subjects involved in research Under This Agreement shall be protected in accordance with 45 CFR Part 46 and with the Recipient's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Office of Public Health and Science (OPHS). The Recipient further agrees to provide certification that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects, in accordance with 45 CFR Part 46 and the Assurance of Compliance.

2. The Recipient shall bear full responsibility for the performance of all work and services involving the use of human subjects Under This Agreement and shall ensure that work is conducted in a proper manner and as safely as is feasible. The Parties agree that Recipient retains the right to control and direct the performance of all work Under This Agreement. Nothing in this Agreement shall be deemed to constitute Recipient or any Sub-Recipient, agent or employee of Recipient, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. Recipient agrees that it has entered into this Agreement and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent consortium without imputing liability on the part of the Government for the acts of the Recipient or its employees.

3. If at any time during the performance of this Agreement, the HHS OTAO determines, in consultation with the OHRP, OPHS, and ASH, that the Recipient is not in compliance with any of the requirements and/or standards stated in Subparagraphs (1) and (2) above, the HHS OTAO may immediately suspend, in whole or in part, work and further payments Under This Agreement until the

Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient fails to complete corrective action within the period of time designated in the OTAO's written notice of suspension, the HHS OTAO may, in consultation with OHRP, OPHS, and ASH, terminate this Agreement in a whole or in part, and the Recipient's name may be removed from the list of those performers with approved Health and Human Services Human Subject Assurances.

B. Human Materials (Assurance of OHRP Compliance)

1. The acquisition and supply of all human specimen material (including fetal material) used Under This Agreement shall be obtained by Recipient in full compliance with applicable Federal, state and local laws and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

2. The Recipient shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted Under This Agreement, by collaborating sites, or by Sub-Recipients identified Under This Agreement, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Recipient.

3. Provision by the Recipient to the HHS OTAO's of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/ Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

C. Research Involving Human Fetal Tissue

All research involving human fetal tissue shall be conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B. The Recipient shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Recipient.

D. Needle Exchange

The Recipient shall not use Agreement funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

E. Care of Live Vertebrate Animals

1. Before undertaking performance of any Agreement involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Recipient shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Recipient shall furnish evidence of the registration to the Contracting Officer.

2. The Recipient shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

3. The Recipient agrees that the care, use, and intended use of any live vertebrate animals in the performance of this Agreement shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

4. If at any time during performance of this Agreement, the HHS OTAO determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Recipient or their Sub-Recipients are not in compliance with any of the requirements and standards stated in Subparagraphs (1) through (3) above, the HHS OTAO may immediately suspend, in whole or in part, work and further payments Under This Agreement until the Recipient or Sub-Recipient corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Recipient or Sub-Recipient fails to complete corrective action within the period of time designated in the OTAO written notice of suspension, the HHS OTAO may, in consultation with OLAW and NIH, terminate this Agreement in whole or in part, and the Recipient's or Sub-Recipient's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Recipient may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. Information concerning this program may be obtained by contacting your regional office or the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

F. Animal Welfare

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm. Primate studies will not begin until the CRO's IACUC and the Recipient's Animal Welfare Department provide final approval of the study protocol.

G. Protection of Personnel Who Work with Nonhuman Primates

All Recipient personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/.

H. Information on Compliance with Animal Care Requirements

Registration with the USDA is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), https://awic.nal.usda.gov/.

The PHS Policy is administered by the OLAW http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service. If the Recipient does not have an assurance and will be utilizing a Sub-Recipient to perform the animal work, then the Recipient and Sub-Recipient must have an Inter-Institutional Assurance in place to allow the Recipient to utilize the assurance of the Sub-Recipient to meet the Government's requirements for assurance. The request for this negotiation of this assurance must be submitted to OLAW by the Government on behalf of the Recipient.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http://awic.nal.usda.gov/final-rules-animal-welfare-9-cfr-parts-1-2-and-3 issued by the USDA under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies http://www.fass.org.

I. Approval of Required Assurance by Law

Under governing regulations, federal funds that are administered by the Department of Health and Human Services, BARDA shall not be expended by the Recipient for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Recipient under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 is submitted by Recipient 30 days prior to commencing research involving live vertebrate animals and approved by the OLAW. Each performance site (if any) must also assure compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities that do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants.nih.gov/grants/olaw/olaw.htm.

Registration with the Select Agent Program for Work Involving the Possession, Use, and/or Transfer of Select Biological Agents or Toxins:

Work involving select biological agents or toxins shall not be conducted Under This Agreement until the Recipient and any affected Sub-Recipients are granted a certificate of registration or are authorized to work with the applicable select agents.

For Recipient or Sub-Recipient awards to domestic institutions who possess, use, and/or transfer Select Agents Under This Agreement, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), DHHS or APHIS, USDA, as applicable, before performing work involving Select Agents, in accordance with 42 CFR Part 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR Part 73, if the final registration certificate is denied.

For Recipient or Sub-Recipient awards to foreign institutions who possess, use, and/or transfer Select Agents Under This Agreement, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR Part 73 for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Recipient must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR Part 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the OTAO, the Recipient shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Recipient must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents Under This Agreement.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

J. Product Approval

The Recipient agrees to comply with cGMP guidelines (21 CFR Parts 210-211, 600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents Under This Agreement.

The Recipient agrees to advise the HHS OTAO and OTTR promptly of any relocation of the Recipient's prime manufacturing facility or the relocation of any Sub-Recipient's facility during the Term. The Recipient also agrees to advise the HHS OTAO and OTTR immediately if at any time during the Term, the items Under This Agreement fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

K. Manufacturing Standards

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of a therapeutic product Under This Agreement unless otherwise agreed upon or as required by the development process (e.g., lab scale experimental manufacturing and pilot scale manufacturing).

If at any time during the Term, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of a therapeutic product Under This Agreement and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by FDA, the Recipient shall have sixty (60) calendar days from the time such material failure is

identified to initiate corrective action designed to cure such material failure within three (3) months. If the Recipient fails to initiate such an action within the sixty (60) calendar day period, then the Agreement may be terminated.

Recipient agrees to make reasonable efforts during the term of this Agreement to enable Baloxavir to be manufactured substantially in the United States. If, based on its reasonable efforts, Recipient is unsuccessful in securing necessary technical objectives or agreements for domestic manufacturing, or if domestic manufacture is not commercially feasible, it will notify the JOC and work to identify alternative solutions to maximize domestically manufactured content.

L. Anti-Bribery and Anti-Corruption

Each Party agrees to perform its obligations Under This Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Agreement, to terminate this Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this Article XVI Paragraph L.

M. Salary Rate Limitation

1. Pursuant to the current and applicable prior HHS appropriations acts, payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date an expense is incurred is an unallowable cost Under This Agreement and shall be addressed in accordance with Article VII.C.

2. For purposes of the salary rate limitation, the terms “direct salary,” “salary”, and “institutional base salary”, have the same meaning and are collectively referred to as “direct salary”, in this clause. An individual’s direct salary is the annual compensation that the Recipient pays for an individual’s direct effort (costs) Under This Agreement. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Recipient. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract, order, or OTAR; it merely limits the portion of that salary that may be paid with Federal funds.

3. The salary rate limitation also applies to individuals under Sub-Recipient agreements. If this Agreement is a multiple-year OTAR, it may be subject to unilateral modification by the OTAO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Agreement funding.

4. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

N. Person-In-Plant

With seven (7) days advance notice to the Recipient in writing from the OTAO/OTAS, the Government may place a person-in-plant in the Recipient's facility for activities associated with this Agreement, who shall be subject to the Recipient's policies and procedures regarding security and facility access at all times while in the Recipient's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a Recipient plant.

O. Reporting Matters Involving Fraud, Waste and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

P. Prohibition on Recipient Involvement with Terrorist Activities

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Recipient to ensure compliance with these Executive Orders and Laws. The Recipient shall ensure that any agreements entered into after the execution of this Agreement with an Affiliate or Sub-Recipient (regardless of tier) for any experimental, developmental, or research work that will be submitted for reimbursement Under This Agreement are consistent with this Paragraph.

Q. Materials Transfers

For distribution to third parties of any material developed Under This Agreement, the Recipient must provide BARDA notice of the requests/transfers in the Recipient's monthly technical report.

R. Inspection and Acceptance

1. The OTAO or the duly authorized representative will perform inspection and acceptance of materials and services to be provided Under This Agreement.

2. For the purposes of this Paragraph, the designated OTTR is the authorized representative of OTAO. The OTTR will assist in resolving technical issues that arise during performance of the Agreement. The OTTR; however, is not authorized to change any Agreement terms or authorize any changes in the SOW or modify or extend the Term, or authorize reimbursement of any costs incurred during performance of the Agreement.

3. Inspection and acceptance will be performed at Recipient or Sub-Recipient's facilities or at:

Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
330 Independence Ave, SW Room G644
Washington, D.C. 20024

ARTICLE XVII: TRANSFERS & ASSIGNMENTS

All transfers and/or assignment will be conducted in a manner that is consistent with the Assignment of Claims Act (31 U.S. Code § 3727) and the Prohibition on transfer of contract and certain allowable assignments (41 U.S.C.A. § 6305).

ARTICLE XVIII: ENTIRE AGREEMENT

Unless otherwise specifically provided, this Agreement and its Attachments embodies the entire understanding between the Parties on the subject matter hereof, and any prior or contemporaneous representations, either oral or written, are superseded. No amendments or changes to this Agreement, including without limitation, changes in the SOW, total estimated cost, and Term, shall be effective unless made in writing and signed by authorized representatives of the Parties.

ATTACHMENT 1:
STATEMENT OF WORK
DATED

Recipient: Genentech, Inc.

Contractual Statement of Work

1) Statement of Work

Independently, and not as an agent of the Government, the Contractor (Genentech) shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

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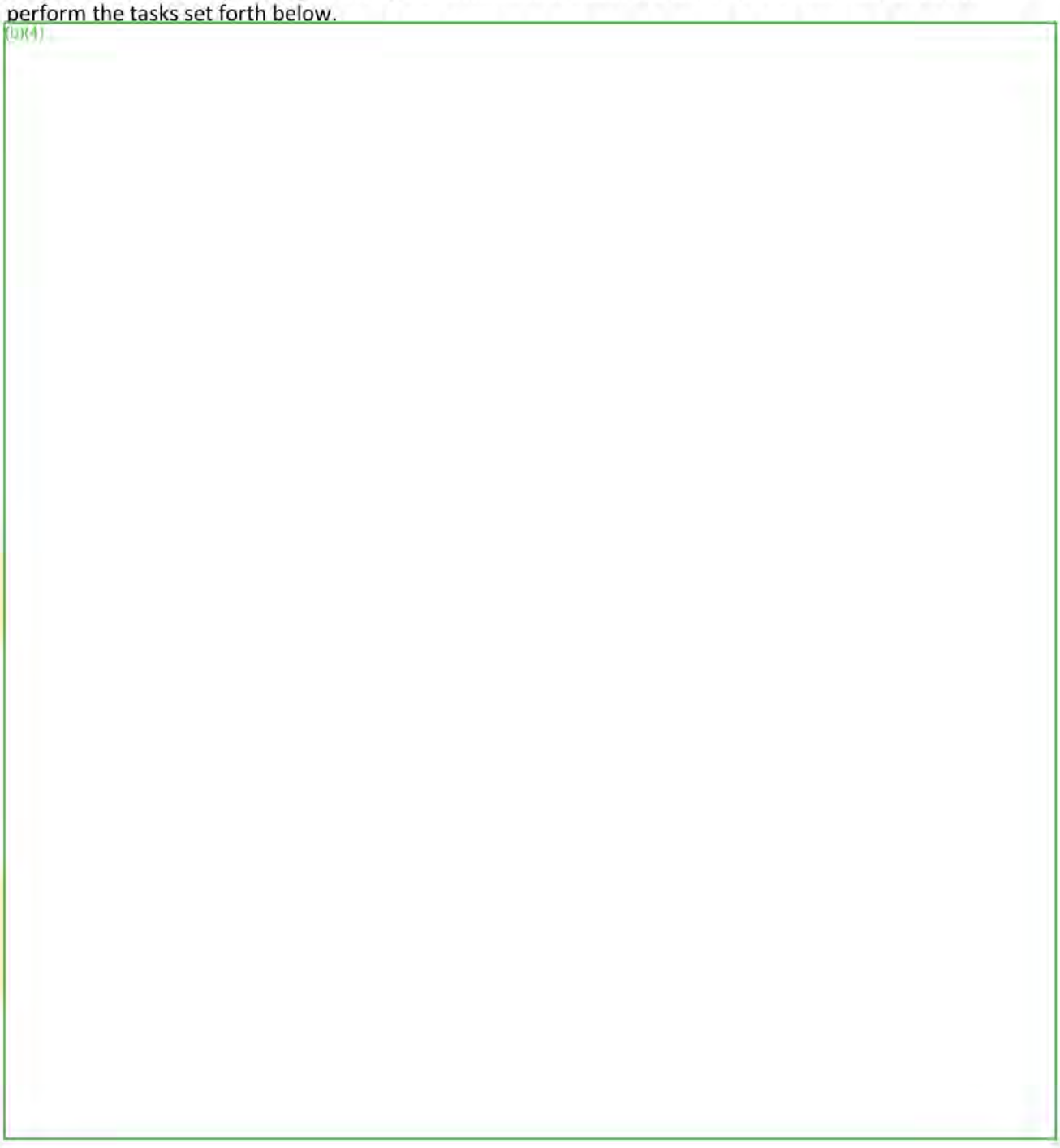

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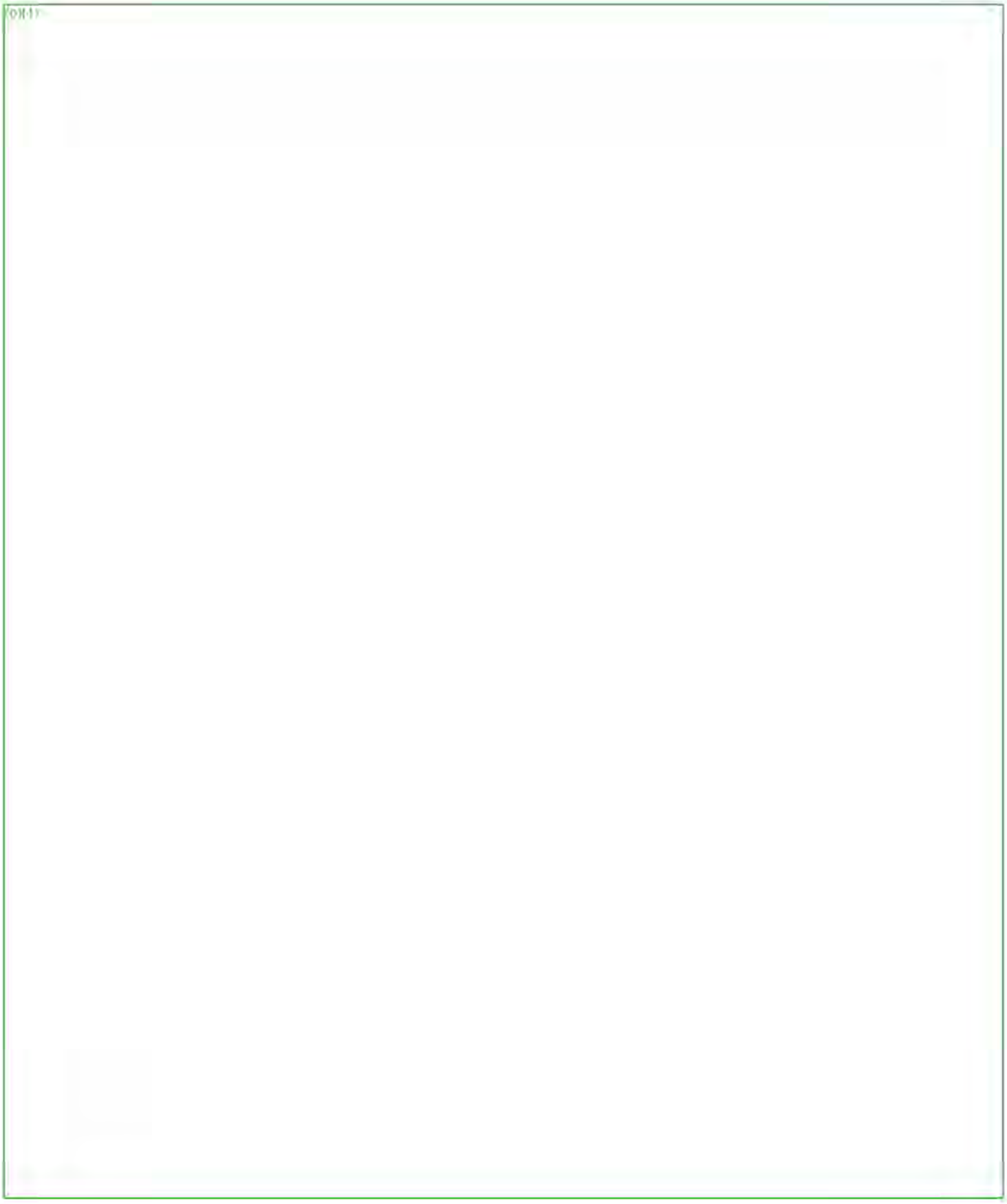

ATTACHMENT 2:
REPORTING REQUIREMENTS

A. PROJECT TELECONFERENCES –Reference Article IV Subsection B1.

B. OTHER MEETINGS - Reference Article IV Subsection B2.

C. REPORT DELIVERABLES

Unless otherwise specified by the OTAO, delivery of reports to be furnished to the Government Under This Agreement (including invoices), shall be delivered electronically along with a concurrent email notification in accordance with Article VII, Paragraph B.

For electronic delivery of final versions of the deliverables listed below, the Recipient shall upload documents into the appropriate folder on **https://eroom.bardatools.hhs.gov/eRoom ("eRoom")** which is the designated USG file sharing system. The USG shall provide two Recipient representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the USG prior to gaining user access. A notification email should be sent to the OTAO, OTAS, and OTTR upon electronic delivery of any documents in accordance with Article VII, Paragraph B.

D. DELIVERABLES

Successful performance of the Agreement shall be deemed to occur upon performance of the work set forth in the SOW set forth in Attachment 1 of this Agreement and upon delivery, as required by the SOW or elsewhere in this Agreement, by the Agreement Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule below:

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
1.	Project Meeting	Every two weeks or as agreed to by the Parties	The Parties will participate in teleconferences every other week to discuss the performance of the Agreement. The Recipient will prepare a proposed agenda and will provide draft-meeting minutes to the OTTR for review and concurrence. The Recipient will send a final version of the meeting minutes to the OTTR. The OTTR will distribute the draft and final version to the OTAS and other BARDA staff. (For avoidance of doubt, financial information is not expected at these updates, which will be technically focused.) BARDA reserves the right to include financial personnel in these Project Meetings, if needed.	• The Recipient provides agenda to the OTTR, OTAO, and the OTAS within 2 business days of meeting. • OTTR (with OTAS concurrence) distributes agenda to BARDA participants prior to meeting. • The Recipient provides meeting minutes within 3 business days of the meeting. • OTTR reviews and comments on minutes within 10 business days.	1 Electronic to OTTR, and OTAS Final will be uploaded into eRoom
		Every third month (Quarterly), if requested by OTTA	The Parties will participate in quarterly face-to-face site visits or teleconferences in Washington, D.C. and/or at work sites of the Recipient to discuss the performance of the Agreement. The meetings will be used to discuss Agreement progress in relation to the Work Breakdown Structure (WBS), Integrated Master Schedule (IMS), and Agreement Performance Reports (APR) as well as study designs, technical, financial, regulatory, and ethical aspects of the Program. These meetings may also include site visits to the Recipient and Sub-Recipient's facilities.	• The Recipient shall provide itinerary and agenda at least 5 business days in advance of site visit. • OTTR review and distributes itinerary and agenda within 3 business days of meeting.	

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
		Roche/BARDA Joint OTAR Oversight Committee meeting (every 6 months or on an *ad hoc* basis as needed)	Members of the JOC will meet approximately every six months as detailed in Article IV. A pre-meeting may be required for larger decisions/to clarify outstanding questions.	• Meeting minutes will be taken by the Recipient and provided to the OTTR, OTAO, and OTAS within 3 business days of the meeting. • OTTR will distribute the minutes to the JOC members and return any BARDA edits or comments to the Recipient within 3 business days of original receipt of the draft minutes. • If changes to the agreement are made, the Recipient will draft a decision memo, provide an updated SOW, and a new budget and provide to BARDA within 3 weeks.	

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
2.	Monthly Status Report	The 30th calendar day of each month following the fractional portion of the initial month and first full month of the OTA award. Monthly reports are due each month within 30 days after the last day of that month, except on the month when the Annual Technical Progress Reports are due. The reporting period will reflect the prior month's activities.	The Monthly Status Report will address the items listed below and cross-referenced to the Work Breakdown Structure (WBS), Scope of Work (SOW), Integrated Master Schedule (IMS), Performance Measurement Baseline Review (PMBR) report, Agreement Performance Reports (APR), and approval strategy. 1. An Executive Summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities. The Executive Summary should be limited to 2-3 pages and highlight critical issues for that reporting period. 2. The report should detail the planned and actual progress of the SOW activities during the period covered, explaining occurrences of any differences between the two, and the corrective steps. 3. The report should list any regulatory submissions relevant to the Medical Countermeasure candidates covered Under This Agreement that have taken place during the reporting period.	Monthly Reports: • The Recipient provides Monthly Status Report deliverables within 30 days after the last day of that month reflecting the prior month's activities. • OTTR and OTAS will review Monthly Reports with Recipient and provide feedback.	1 Electronic Copy to OTTR and OTAS Final will be uploaded into eRoom

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
3.	Integrated Master Schedule (IMS)	Within 60 days of OTA award and updated monthly	The Recipient will provide an IMS and monthly status updates in the monthly report to reflect changes in schedule, performance, and critical path. The Recipient will include BARDA Portfolio Progress Milestones in their IMS and provide monthly updates within their IMS. The IMS will be a standalone schedule containing only those activities that are applicable to the SOW. Individual project schedules for the assets within the Portfolio will also be provided on a monthly basis.	• The Recipient shall provide an IMS within 60 days of OTA award and updated within 30 days after the last day of each month. • IMS shall be in both PDF and Microsoft Project Form. • BARDA shall provide the Recipient with a written list of concerns in response to the Recipient's submitted IMS, and the Recipient must address, in writing, all concerns raised by BARDA within 10 business days of Recipient's receipt of this list of concerns.	1 Electronic Copy (PDF and Microsoft Project Schedule (.mmp) format to OTTR and OTAS; Upload to eRoom.
4.	Financial Status Report	The 30th calendar day of each month following the fractional portion of the initial month and first full month of the OTA award. Financial Status Reports are updated monthly within 30 days after the last day of that month in the Project Status Report.	Recipient will provide a monthly Financial Status Report at an agreed upon WBS level using a format mutually agreed upon by the Parties.	• Recipient shall provide a Financial Status Report within 30 days after the last day of that month. • BARDA may raise, in writing, concerns for Recipient to address; Recipient must address, in writing, all concerns raised by BARDA.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
5.	Risk Management Plan	90 days following OTA award and updated yearly (additional submissions as requested by OTAS or OTTR)	The Recipient will provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule and performance objectives. The Risk Management Plan will include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.	• The Recipient will provide a Risk Management Plan 90 days following OTA award and update Quarterly in their Monthly or Annual Project Status Reports. • BARDA will provide the Recipient with a written list of concerns (if any exist) in response to the Recipient's submitted Risk Management Plan, and Recipient must address in writing all concerns raised by BARDA within 20 business days of Recipient's receipt of this list of concerns.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.
6.	Deviation Notification and Mitigation Strategy	within 10 days of identification	Process for changing IMS activities associated with cost and schedule as baselined at the PMBR.	• The Recipient will notify BARDA of significant changes to the IMS. This includes increases in cost above 10% or schedule slippage of more than 30 days for activities at the WBS level, which would require a POP extension. The Recipient will provide a high level management strategy for risk mitigation.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.
7.	In-Process Review Presentation	Annual or event driven review following completion of a pre-defined stage of product development and prior to initiation of a new stage	The Recipient will provide a presentation to BARDA and other Intergovernmental agency invitees on the Portfolio Progress at an In-Process Review meeting.	• The Recipient will provide an update to technical progress made towards Portfolio Progress at an In-Process Review meeting and provide the presentation to BARDA 10 business days prior to the meeting.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
8.	Incident Report	Within 24 or 48 hrs of activity or incident	The Recipient will communicate and document all critical programmatic concerns, risks or potential risks with BARDA within 48 hours. Recipient shall communicate via email or telephone. In addition, the Recipient will report to the government any activity or incident that is in violation of established security standards or indicates the loss or theft of government products within 24 hrs of knowledge of activity or incident. Recipient will communicate via email, oral or written communication.	• Recipient will notify (orally or in writing) BARDA OTTR and OTAS within 48 hrs of Recipient identifying a critical project risk or potential risk and within 24 hrs for Security activities or incident. • Recipient will provide additional updates within 48 hrs of additional developments, additional information and/or understanding. • The Recipient will submit within 5 business days a Corrective Action Plan (if deemed necessary by either Party) to address any potential issues. • If corrective action is recommended, the Recipient must address in writing its consideration of concerns raised by BARDA • The Recipient will address BARDA's concerns in writing within 5 business days.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
9.	Draft and Final Technical Progress Report	Draft 75 calendar days before and Final shall be submitted on or before the completion date of the POP	A draft of Final Technical Progress Report containing a summation of the work performed and the results obtained for the entire Agreement POP. The draft report shall be duly marked as 'Draft'. The Final Technical Progress Report incorporating the feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire Agreement POP. This final report shall detail, document and summarize the results of the entire Agreement. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. The final report shall be duly marked as 'Final'.	• The Recipient shall provide a draft Technical Progress Report 75 calendar days before the end of the POP and the Final Technical Progress Report shall be submitted on or before the completion date of the POP. • Sub-Recipient prepared reports will be submitted to the OTTR and OTAS for review and comment no later than 5 business days after receipt by the prime Recipient. • OTTR provides edits and additional feedback to draft report within 15 calendar days of receipt, which the Recipient will consider incorporating into the Final Technical Progress Report. • The Recipient will submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the Agreement. • The Recipient will submit one (1) copy of a comprehensive final report to the OTAS and one (1) copy (one electronically on a CD) to the OTTR.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
10.	Study Protocols	At least 10 business days prior to FDA Submission	The Recipient will provide Pre-Clinical/Non-Clinical/ Clinical Trial Protocols to BARDA for evaluation, prior to FDA submission. The OTAS and OTTR reserve the right to request within the POP a non-proprietary Study Protocol for distribution within the United States Government (USG).	• The Recipient will submit draft and final protocols to BARDA for review and comment. • If the draft protocols are to be submitted to the FDA, BARDA review will take place prior to FDA submission. • BARDA will return comments to Recipient on the protocols no later than 10 business days from the date of receipt. • The Recipient will address, in writing, all concerns raised by BARDA. • The Recipient is not required to make any protocol revisions based on BARDA's concerns and/or recommendations. • In the event that BARDA disagrees with the final study protocol design, BARDA will notify the Recipient of non-concurrence in writing. • Final FDA submissions shall be submitted to BARDA concurrently or no later than 5 calendar days after its submission to FDA.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
11.	Study Reports	Within 5 (five) calendar days of the reports being available to Recipient and 15 business days prior to anticipated submission to FDA	The OTAS and OTTR reserve the right to request within the POP a non-proprietary Study Report for distribution within the USG. The Recipient will submit an interim study report to BARDA for any severable discrete work segments. If funding for a severable study is scheduled in two separate periods of performance than an interim study report is due on or before the completion date of the POP.	• The Recipient will provide Draft and Final Pre-Clinical/Non-Clinical Study Reports to BARDA for review and comment within 2 (two) calendar days of these reports being available to the Recipient. • The Recipient will submit proposed Pre-Clinical/Non-Clinical Study Report to BARDA at least 15 business days prior to the anticipated FDA Submission date. • If corrective action is recommended, Recipient will use reasonable efforts to address, in writing or by corrective action, all concerns raised by BARDA prior to FDA submission. • Final FDA submissions shall be provided to BARDA concurrently or no later than 2 business days of its submission to FDA.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.
12.	Regulatory Meeting Notification	Within 24 hours of the anticipated scheduling Type A, B or C meetings OR within 48 hours of meeting occurrence for ad hoc meetings	The Recipient will forward the dates and times of any anticipated meeting with the regulatory agency to BARDA and seek to arrange for appropriate BARDA staff to attend the regulatory meetings relevant to BARDA-funded work. BARDA staff shall include up to a maximum of four people.	• The Recipient will notify BARDA of an upcoming meeting with the regulatory agency within 48 hours of being informed that a meeting is scheduled.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
13.	Regulatory Correspondence and Meeting Minutes	Within three (3) business days of receiving correspondence (as described in the Description of Deliverables) from the Regulatory Agency	The Recipient will forward Recipient and FDA-issued draft minutes and final minutes of any meeting with the Regulatory Agency to BARDA relevant to the Portfolio Program. All documents shall be duly marked as either 'Draft' or 'Final'.	• The Recipient provides Regulatory correspondence and meeting minutes (as described in the Description of Deliverables) within three (3) business days of receipt of the meeting or correspondence.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.
14.	Regulatory Submissions	At least 10 calendar days prior to anticipated submission to FDA	The Recipient will provide BARDA the opportunity to review and comment upon regulatory documents before anticipated submission to the Regulatory Agency. Such documents shall include responses/comments/questions that the Regulatory Agency has passed on to the sponsor regarding the investigational compounds in this Agreement as well as the name and address of the IRBs involved in clinical studies. All documents will be duly marked as either 'Draft' or 'Final'. For avoidance of doubt, the Recipient is not required to provide to BARDA routine, general correspondence or information amendments (e.g. routine emails).	• The Recipient submits draft Regulatory Meeting Briefing Packets to BARDA at least 10 calendar days prior to anticipated submission to the Regulatory Agency. BARDA will provide comments to Recipient within 5 business days of receiving the briefing. • If corrective action is recommended, Recipient will address, in writing its considerations of all concerns raised by BARDA. • The Recipient will consider revising documents to address BARDA's concerns and/or recommendations prior to submission to regulatory authorities. • Final Regulatory submissions shall be submitted to BARDA concurrently or no later than 5 business days of its submission to FDA.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
15.	FDA Audits	Within 10 business days of a scheduled audit or within 48 hours of an *ad hoc* site visits/audits if the FDA did not provide advanced notification	In the event of an FDA inspection that occurs as a result of this Agreement and for the investigational compound, or for any other FDA inspection that has the reasonable potential to impact the performance of this Agreement, the Recipient will provide BARDA with an exact copy (non-redacted) of the FDA Form 483, and the Establishment Inspection Report (EIR). Recipient shall provide the OTTR and OTAS copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report within 10 business days, status updates during the plans execution, and a copy of all final responses to the FDA. The Recipient shall also provide redacted copies of any FDA audit report received from Sub-Recipients that occur as a result of this Agreement or for this product within five business days of receiving correspondence from the FDA and/or third party. The Recipient shall make arrangements, where practical, for a BARDA representative(s) to be present during the final debrief by the regulatory inspector for audits of the Recipient.	• The Recipient will notify the OTTR and OTAS within 10 business days of a scheduled audit or within 24hours of receiving notice of an ad hoc site visit(s)/audit(s) if the FDA did not provide advanced notification. • The Recipient will also provide copies of any FDA audit report received from Sub-Recipients that occur as a result of this Agreement or for the investigational compound within five business days of receiving correspondence from the FDA and/or third party. • Within 10 business days of audit report, the Recipient will provide OTAS with a plan for addressing areas of nonconformance, if any exist.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
16.	QA Audit Reports	5 business days of report completion	The Recipient will inform the OTTR and OTAS of upcoming, ongoing, or recent audits/site visits of Sub-Recipients as a result of this Agreement and for the investigational compound, or for any other FDA inspection that has the reasonable potential to impact the performance of this Agreement as part of the weekly communications, including goals and agenda. BARDA reserves the right to participate in the audits. Upon completion of the audit/site visit the Recipient shall provide a report capturing the findings, results and next steps in proceeding with the Sub-Recipient. If action is requested of the Sub-Recipient, details addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. Recipient shall provide responses from the Sub-Recipients to address these concerns and plans for corrective action execution For avoidance of doubt, as our Sub-Recipients may be involved in other activities for the Recipient, the reportable audit information will only pertain to that which materially affects those programs funded under the Portfolio partnership.	• The Recipient will inform the OTTR and OTAS of upcoming, ongoing or recent audits/site visits of Sub-Recipients. • The Recipient will notify the OTTR and OTAS within 5 business days of report completion.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

#	Type of Deliverable	Frequency/Time Periods	Description of Deliverable	Reporting Procedures	Quantity/Form
17.	BARDA Audit	*Ad Hoc*	The Recipient shall accommodate for periodic or *ad hoc* site visits by BARDA. If BARDA, Recipient or other parties identifies any issues during an audit, Recipient shall capture the issues, identify potential solutions and provide a report to BARDA.	• If BARDA, the Recipient or other parties identifies any issues during an audit, Recipient shall capture the issues, identify potential solutions and provide a report to BARDA within 10 business days. • The OTTR and OTAS will review the deliverable and provide a response to Recipient. • Once any corrective action undertaken by Recipient is completed, Recipient will provide a final report to BARDA.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.
18.	Animal Model or Other Technology Transfer Package	Within 10 business days of request by OTAS/OTTR	The Recipient shall provide Animal Model or Other Technology Transfer Package relevant data.	• The Recipient will provide Animal Model or other Technology Transfer Package within 10 business days of request by OTAS/OTTR.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.
19.	Raw Data or Data Analysis	Within 20 business days, or as available, after receipt of request by OTAS/OTTR	The Recipient shall provide Raw Data or Data Analysis for review by BARDA, if requested. (For avoidance of doubt, clinical data will be subject to human subject privacy policies.)	• The Recipient will provide Raw Data or Data Analysis within 20 business days (or as available) of request by OTAS/OTTR.	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.
20.	Press Releases	5 days prior to release	Recipient agrees to accurately and factually represent the work conducted Under This Agreement in all press releases	• Recipient shall ensure that BARDA has received an advanced copy of any press release concerning this Agreement not less than 5 business days prior to the issuance of the press release	1 Electronic Copy to OTTR and OTAS; Upload to eRoom.

ATTACHMENT 3

AFFILIATE LIST